

UNITED STATES DISTRICT COURT FOR THE
NORTHERN DISTRICT OF ILLINOIS

IN RE: TESTOSTERONE) Case No. 14 C 1748
REPLACEMENT THERAPY)
PRODUCTS LIABILITY LITIGATION) MDL No. 2545
)
This document relates to all cases) Judge Matthew F. Kennelly

**REPLY IN SUPPORT OF BESINS HEALTHCARE, S.A.'S AND BESINS
HEALTHCARE INC.'S MOTION TO DISMISS**

INTRODUCTION

Plaintiffs' Second Amended Master Long-Form Complaint and Jury Demand ("Master Complaint") fails to plead specific factual allegations sufficient to establish a claim against Defendants Besins Healthcare, S.A. ("Besins, S.A.") and Besins Healthcare Inc. ("Besins Inc.") (collectively "the Besins Defendants"). In an attempt to evade this requirement, the Master Complaint lumps the Besins Defendants together with a wholly different company – AbbVie Inc. ("AbbVie"). As a result, it is not clear what Plaintiffs specifically allege as to the Besins Defendants. Plaintiffs' Opposition provides no justification for such deficient pleading but instead ignores the issue.

Further, the Master Complaint fails to plead sufficient facts to support the exercise of jurisdiction over Besins, S.A. Plaintiffs' Opposition concedes the Court does not have general jurisdiction over Besins, S.A. Although Plaintiffs argue that Besins, S.A. nonetheless is subject to jurisdiction anywhere in the United States because of the manufacturing agreement between Besins, S.A. and AbbVie, the United States Supreme Court has rejected such an argument, and this Court should do likewise.

ARGUMENT

I. The Master Complaint Fails To Make Clear, Concise, And Direct Allegations Against The Besins Defendants.

"Each allegation" in a pleading "must be simple, concise, and direct." Fed. R. Civ. P. 8(d)(1). This is so the defendant gets "fair notice of what the . . . claim is and the grounds upon which it rests." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)). "[T]he pleading must contain something more . . . than . . . a statement of facts that merely creates a suspicion [of] a legally cognizable right of action."

CHARLES ALLEN WRIGHT, ET AL., 5 Fed. Prac. & Proc. Civ. § 1216 (3d ed. 2015). The Master Complaint does not satisfy the pleading standard with respect to the Besins Defendants.

In their Opposition, Plaintiffs concede they are not pursuing claims against the Besins Defendants for failure to warn, negligent misrepresentation, breach of implied warranty, breach of express warranty, fraud, or consumer protection. Pls.’ Opp. at 3 n.4. But nothing in the Master Complaint itself put the Besins Defendants on notice that the claims and allegations against them were so limited. This illustrates the pervasive problem running throughout the Master Complaint: the wholesale failure to plead allegations with sufficient specificity as to the Besins Defendants.

This confusion is compounded by the fact that the Master Complaint defines “AbbVie” throughout the Complaint to refer to a group of independent defendants that includes the Besins Defendants. *See, e.g.*, Master Complaint ¶28. As noted in the Besins Defendants’ opening brief, only 7 of the 657 paragraphs of the Master Complaint specifically reference either Besins Inc. or Besins, S.A. *See* Master Complaint at ¶¶25–29, 58, 127. Apart from those seven paragraphs, there was no way for the Besins Defendants to identify the allegations that relate to them, and indeed, Plaintiffs concede that the vast majority do not. This vague pleading, whether sloppy or intentional, is impermissible and is grounds for dismissal. *See, e.g.*, *Thomas-Wise v. Nat'l City Mortg. Co.*, 14 C 3460, 2015 WL 641770, at *4 (N.D. Ill. Feb. 13, 2015) (dismissing complaint where the “allegations lump everyone together as ‘Defendants’ instead of specifically identifying which defendant did what.”) (citing *Bank of Am., N.A. v. Knight*, 725 F.3d 815, 818 (7th Cir. 2013)); *Omran v. United States*, No. 14-13881, 2015 WL 1523587, at *6 (D. Mass. Mar. 31, 2015) (dismissing case for failure to comply with Rule 8 where Plaintiff “collectively asserted his claims against the Defendants.”).

The Master Complaint's wholesale failure to satisfy the Rule 8 pleading standard, alone, is grounds to grant the Motion to Dismiss because the vague allegations have not provided notice to the Besins Defendants as required by the Rules and the Constitution.

II. The Master Complaint Fails To Plead Viable Design Defect And Redhibition Claims Against The Besins Defendants.

Plaintiffs now admit they are pursuing only two substantive causes of action against the Besins Defendants—design defect and redhibition.¹ But the Master Complaint fails to support even these two remaining claims with the requisite specific facts needed to avoid dismissal pursuant to Fed. R. Civ. P. 12(b)(6). *See McCauley v. City of Chicago*, 671 F.3d 611, 616 (7th Cir. 2011) (requiring plaintiff “to ‘provid[e] some specific facts’ to support the legal claims asserted in the complaint.” (quoting *Brooks v. Ross*, 578 F.3d 574, 581 (7th Cir. 2009)). As the Seventh Circuit has warned, “courts should not accept as adequate abstract recitations of the elements of a cause of action or conclusory legal statements.” *Brooks*, 578 F.3d at 581.

A. The Master Complaint Does Not State A Viable Design Defect Claim Against Either Besins Defendant.

The Besins Defendants do not, and have never, marketed AndroGel in the United States. AbbVie (and AbbVie’s predecessors in interest) has marketed and sold AndroGel in the United States and has been responsible for any alleged safety-related issues in the United States. Nothing in the Master Complaint pleads to the contrary. As a result, the Court should dismiss Plaintiffs’ design defect claims against the Besins Defendants.

Plaintiffs’ Opposition cites only a handful of paragraphs making general design defect allegations against the Besins Defendants. The Opening Brief addressed each of these

¹ As Plaintiffs’ Opposition acknowledges, Pls.’ Opp at 3 and n.4, the remaining Counts of the Master Complaint – Plaintiffs’ Tenth, Eleventh, Twelfth, Thirteenth, and Fourteenth Claims – are not independent causes of action but instead require a finding of liability as to one of Plaintiffs’ substantive claims. Dismissal of the two claims Plaintiffs now claim they are pursuing against the Besins Defendants would also require dismissal of these collateral claims.

allegations at pages 6-7. The Master Complaint alleges both Besins Defendants “engaged in the research, development, design, testing, manufacture, sales, marketing, and/or distribution of . . . AndroGel,” and that a Besins entity holds intellectual property rights for AndroGel. Master Complaint at ¶¶25, 26. Yet the Master Complaint does not specify which Besins entity engaged in any particular act, nor does it allege that Plaintiffs sustained injury as a result of any actions that can be specifically attributed to the Besins Defendants. At most, Plaintiffs claim that the Besins entities played some unspecified role in developing AndroGel, and that the product is “defective.” This is not enough to support a claim for design defect. *Ball v. Takeda Pharm. Am., Inc.*, 963 F. Supp. 2d 497, 505 (E.D. Va. 2013) (“[a] bare allegation of a ‘defect’ is no more than a legal conclusion.”) (citing *Ojeda v. Louisville Ladder Inc.*, 410 Fed. App’x. 213, 215 (11th Cir. 2010); *United States v. Stephens*, 445 F.2d 192, 198 (3d Cir. 1971) (Aldisert, J., concurring)). To the contrary, Plaintiffs must allege “enough facts to state a claim to relief that is plausible on its face.” *Twombly*, 550 U.S. at 570. The Complaint’s “factual content” must allow “the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

The Master Complaint contains no facts concerning the Besins Defendants’ roles in designing AndroGel or what their contributions were to that design. Indeed, at various portions of the Master Complaint, each of the Besins Defendants, Unimed Pharmaceuticals, LLC, AbbVie Inc., Abbott Laboratories, AbbVie Products, LLC, and Solvay S.A. are implicated in design work on AndroGel, with little distinction between each of these defendants. Master Complaint ¶¶25, 26, 58(a), 59(a-b).

Nor does the Master Complaint identify what renders AndroGel defective for its intended purpose, or how the Besins Defendants could have altered its design to make it safer. These

failings render the Master Complaint's allegations inadequate, particularly in light of the importance of these facts to design defect claims for many of the jurisdictions in which plaintiffs are to proceed with their claims. *See, e.g., Piltch v. Ford Motor Co.*, 778 F.3d 628, 632 (7th Cir. 2015) (under Indiana law, to show design defect, plaintiff must "show that another design not only could have prevented the injury but also was cost-effective under general negligence principles") (quoting *Pries v. Honda Motor Co.*, 31 F.3d 543, 545–46 (7th Cir.1994)); *Eckhardt v. Qualitest Pharms., Inc.*, 751 F.3d 674, 679 (5th Cir. 2014) (to prove strict liability design defect under Texas law, "plaintiff must prove that 'a safer alternative design existed'") (quoting *Timpte Indus., Inc. v. Gish*, 286 S.W.3d 306, 311 (Tex. 2009)); *Mendez v. Shah*, 28 F. Supp. 3d 282, 297-98 (D.N.J. 2014) (on a design defect claim under New Jersey law, "a plaintiff must plead either that the product's risk outweighs its harm, or that an alternate design exists"). Plaintiffs instead merely seem to suggest that AndroGel has certain medical risks, while at the same time the Master Complaint concedes the FDA continues to approve AndroGel for the treatment of hypogonadism.

Even giving these allegations the benefit of the doubt for the purposes of a Rule 12(b)(6) motion, these allegations of risk do not establish that AndroGel is defectively designed. Nowhere does the Master Complaint, which focuses solely on administration of AndroGel and other TRT products to men on the basis that they have "Low T," indicate that AndroGel is so risky that it lacks medical usefulness. *See, e.g., Restatement (Third) of Torts: Product Liability § 6(c); see also Madsen v. Am. Home Prods. Corp.*, 477 F. Supp. 2d 1025, 1037 (E.D. Mo. 2007) (where plaintiff failed to show that "reasonable health-care providers, knowing the risks and benefits, would not have prescribed phentermine, fenfluramine or dexfenfluramine to any class of patients," design defect claim failed); *Gebhardt v. Mentor Corp.*, 191 F.R.D. 180, 185 (D.

Ariz. 1999) (applying Restatement Section 6(c) and granting defendant judgment on product defect claim). And nowhere does the Master Complaint make any allegations of the risks of AndroGel in connection with hypogonadism, the condition for which it was originally developed. Such a flimsy, ill-pled cause of action is insufficient to keep the Besins Defendants in this MDL when Plaintiffs cannot even articulate what, if anything, the Besins Defendants did wrong. The Master Complaint fails to allege a plausible claim against the Besins Defendants for a design defect, and the Besins Defendants should be dismissed from this MDL.

B. The Master Complaint Does Not State A Viable Redhibition Claim Against Either Besins Defendant.

Redhibition is a civil action that only exists under Louisiana law and for which a successful Louisiana Plaintiff may only recover economic damages. *See, e.g., Averette v. Bayer Healthcare Pharms. Inc.*, 2014 U.S. Dist. LEXIS 39347, *6 (E.D. La. Mar. 25, 2014). “A plaintiff who seeks the rescission [sic] of a sale in redhibition must prove: 1) the thing sold is absolutely useless for its intended purpose or that its use is so inconvenient that it must be supposed that he would not have bought it had he known of the defect; 2) that the defect existed at the time he purchased the thing, but was neither known or apparent to him; 3) that the seller was given the opportunity to repair the defect.” *Dalme v. Blockers Manufactured Homes, Inc.*, 779 So. 2d 1014, 1028 (La. App. 3 Cir. Jan. 25, 2001). There are only six cases currently pending in the MDL where either Besins entity has been sued by a Louisiana Plaintiff, and only five of those cases bring a claim for redhibition. Even as to these five cases, there is no basis to keep the Besins Defendants in this MDL because they have failed to plead a viable redhibition claim.

The Master Complaint makes the bare allegation that AndroGel was “useless” for its intended purpose but simultaneously acknowledges the FDA continues to approve its use for the

treatment of hypogonadism, and makes no claim that AndroGel is ineffective for that use. Further, there is no allegation that any Louisiana Plaintiff contacted either the Besins Defendants or AbbVie prior to filing suit, so as to give the Defendants an opportunity to cure the alleged defect as required by Louisiana law. As a result, Plaintiffs have failed to plead multiple elements of redhibition, and those claims must be dismissed.

Finally, even if Plaintiffs were correct that such a claim was cognizable as to Besins, S.A. as the “manufacturer” of AndroGel, the Court should still dismiss all redhibition claims against Besins Inc. The Master Complaint does not allege (nor could it) that Besins Inc. manufactured AndroGel for sale in the United States. Nor does it allege that Besins Inc. ever sold AndroGel. Because redhibition is limited to *sellers* of a product, and Besins Inc. does not manufacture or sell AndroGel, all redhibition claims against it must be dismissed. *See La. C.C. Art. 2520* (2015) (“The *seller* warrants the buyer against redhibitory defects, or vices, in the thing sold.”); *Alston v. Fleetwood Motor Homes of Ind., Inc.*, 480 F.3d 695, 699 (5th Cir. 2007).

III. The Master Complaint Does Not Plead Facts Sufficient To Support The Exercise Of Personal Jurisdiction Over Besins, S.A.

Plaintiffs concede Besins, S.A. is not subject to general personal jurisdiction in any United States jurisdiction. Plaintiffs nevertheless try to convince the Court to exercise specific jurisdiction on the theory that Besins, S.A. entered into an agreement allowing Unimed Pharmaceuticals (and now AbbVie) to sell AndroGel in the United States. But Plaintiffs conveniently ignore that Besins, S.A.: 1) did not sell the product in the United States; 2) did not market AndroGel for sale in the United States; 3) did not distribute AndroGel throughout the United States; and 4) played no role in the regulatory process for AndroGel. Rather, Plaintiffs argue specific jurisdiction lies in every state by virtue of the fact that Besins, S.A. manufactures

AndroGel for AbbVie and therefore knew that AndroGel would be sold throughout the United States. This is not enough.

For specific jurisdiction to be proper, Besins, S.A.’s “*suit-related conduct* must create a *substantial connection*” with a *particular* state. *Walden v. Fiore*, ___ U.S. ___, 134 S. Ct. 1115, 1121 (2014) (emphasis added); *RAR, Inc. v. Turner Diesel, Ltd.*, 107 F.3d 1272, 1277 (7th Cir. 1997). A foreign corporation’s awareness, or even intent, that its products will be sold in the United States is insufficient to confer jurisdiction in any particular state. *McIntyre Mach., Ltd. v. Nicastro*, ___ U.S. ___, 131 S. Ct. 2780 (2011) (“*Nicastro*”); *see also Appjigger GmbH v. Blu Products, Inc.*, No. 14 C 9650, 2015 WL 3463413, at *4-6 (N.D. Ill. May 29, 2015).

Moreover, jurisdiction cannot be conferred through the actions of a third party. *Advanced Tactical Ordnance Sys., LLC v. Real Action Paintball, Inc.*, 751 F.3d 796, 801 (7th Cir. 2014) (“the relation between the defendant and the forum ‘must arise out of contacts that the ‘defendant *himself*’ creates with the forum’”) (quoting *Walden*, 134 S. Ct. at 1122 (emphasis in original)). In other words, *AbbVie’s* actions do not provide a basis for jurisdiction over *Besins, S.A.* Yet that is precisely what Plaintiffs would have the Court do.

Plaintiffs do not cite any case where the only relevant contact supporting specific jurisdiction was a general awareness that the product would be sold by a third party in the United States. Plaintiffs’ reliance on *Original Creations, Inc. v. Ready Am., Inc.*, 836 F. Supp. 2d 711 (N.D. Ill. 2011) is misplaced. *Original Creations* was a patent infringement suit. Defendant was headquartered in California and sold the allegedly infringing items *directly* to Illinois residents through an interactive website. Despite these direct sales, the Court found sales through the internet alone insufficient to establish personal jurisdiction in Illinois. The Court found it had personal jurisdiction only because the defendant targeted two Illinois-based distributors, with a

“clearly defined distribution network” in Illinois, to sell its products in Illinois. *Id.* at 717. Indeed, the Court noted that *Nicastro* “dispels the notion that merely placing goods into the stream of commerce always indicates purposeful availment.” *Id.* Even though “[t]he defendant in *Nicastro* engaged a distributor in the U.S. to market *its products throughout the country*,” the Supreme Court “found that such general marketing efforts fell far short of ‘purposefully directing’ activities at the forum state.” *Id.* (quoting *Nicastro*, 131 S.Ct. at 2790). *Nicastro* is exactly like this case. As alleged in the Master Complaint, Besins, S.A. has agreed to manufacture AndroGel for AbbVie. AbbVie alone has the right to market, sell, and distribute AndroGel in the United States. Besins, S.A.’s involvement ends when it delivers AndroGel made according to agreed specifications to AbbVie. This case is thus indistinguishable from *Nicastro*. As a result, this Court should follow *Nicastro* and dismiss all claims against Besins, S.A.²

CONCLUSION

For the foregoing reasons, Defendants Besins Healthcare, S.A. and Besins Healthcare Inc. respectfully request that the Court grant their motion and dismiss all claims against them with prejudice.

² Because Besins, S.A.’s involvement, even under the allegations of the Master Complaint, is so limited, there is also no point in granting Plaintiffs any jurisdictional discovery for the purposes of this Motion. See, e.g., *Rawlins v. Select Specialty Hosp. of Nw. Indiana, Inc.*, No. 13 C 7557, 2014 WL 1647182, at *6 (N.D. Ill. Apr. 23, 2014) (failure to make prima facie showing of personal jurisdiction compels denial of request for jurisdictional discovery). Even if discovery were considered, the irrelevance of the matters that Plaintiffs seek discovery on—such as insurance plans’ formularies in various states, which have little or nothing to do with Besins, S.A.’s suit-related conduct—provides another reason not to grant the discovery that Plaintiffs seek in the alternative.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Christopher R. Boisvert, hereby certify that on August 21, 2015, the foregoing document was filed via the Court's CM/ECF system, which will automatically serve and send email notification of such filing to all registered attorneys of record.

/s/ Christopher R. Boisvert